

Message

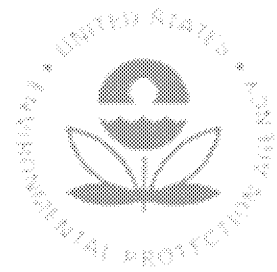
From: Kausch, Jeannine [Kausch.Jeannine@epa.gov]
Sent: 9/1/2016 2:21:25 AM
To: Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]
Subject: FW: For your review -- OPP Update -- Wolbachia EUP Aegypti Mosquitoes
Attachments: Wolbachia pipientis wAlbB Strain EUP Amendment Extension Letter & Labeling_88877-EUP-2_08-30-2016.pdf; BPPD Response to Comments_88877-EUP-2_08-30-2016.pdf; Wolbachia wAlbB EUP Extension PC & HH Assessment_05-09-2016.pdf; Wolbachia wAlbB EUP Extension_Eco Assessment_05-10-2016.pdf; Section G-Wolbachia-EUP-UKY-Final_05-04-2016.pdf

Hi Elizabeth,

Again, sorry for the delayed response. The OPP Update on the FIFRA section 5 application (*Wolbachia* in *Aedes aegypti*; 88877-EUP-2; University of Kentucky) that I believe is going to go out soon (if it is not out already) is below. I am also attaching the science reviews, response to comments document, and amendment/extension letter and labeling that are associated with this experimental use permit. The FIFRA section 3 application (*Wolbachia* in *Aedes albopictus*; 89668-U; MosquitoMate) is still under review. Not sure when this one will be done, but I think we are aiming for some time before the March 2017 PRIA due date.

I hope this helps.

Thanks,
Jeannine



Jeannine Kausch
U.S. EPA Office of Pesticide Programs
1200 Pennsylvania Avenue NW (7511P)
Washington, DC 20460-0001
703.347-8920
kausch.jeannine@epa.gov

From: Overstreet, Anne
Sent: Wednesday, August 31, 2016 10:16 AM
To: McNally, Robert <McNally.Robert@epa.gov>
Cc: Kausch, Jeannine <Kausch.Jeannine@epa.gov>
Subject: FW: For your review -- OPP Update -- Wolbachia EUP Aegypti Mosquitoes

Just an FYI – Rick’s final edits. We’re shooting for next week on this one once we confirm that documents have been loaded into the docket. Do we know if Earl’s folks have agreed to expedite CBI review? Would next Thursday work for the launch?

A.

From: Sisco, Debby
Sent: Wednesday, August 31, 2016 10:10 AM
To: Strauss, Linda <Strauss.Linda@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>; Keltz, Colleen <Keltz.Colleen@epa.gov>; Han, Kaythi <Han.Kaythi@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>
Subject: FW: For your review -- OPP Update -- Wolbachia EUP Aegypti Mosquitoes

See Rick's note below and highlighted edit.

EPA Grants Extension of Experimental Use Permit for 'Wolbachia Mosquito'

EPA has approved the amendment and extension of an existing experimental use permit (EUP) for *Wolbachia pipientis*-infected *Aedes aegypti* mosquitoes. *Wolbachia* are naturally occurring bacteria commonly found in most insect species, but not in the *Aedes aegypti*. The EUP was issued to the University of Kentucky's Department of Entomology (UKDE) in October 2015 for limited testing in Fresno County, California. The updated EUP authorizes testing only in California and Florida to evaluate the *Wolbachia pipientis* bacteria's effectiveness in suppressing and eliminating *Aedes aegypti* mosquitoes at particular sites in Fresno and Orange County in California and Monroe County in Florida.

Wolbachia pipientis are bacteria that generally do not occur in wild populations of *Aedes aegypti*. This strain of *Wolbachia* is extracted from *Aedes albopictus* embryos and microinjected into *Aedes aegypti* embryos. Male mosquitoes are separated from female mosquitoes and shipped to testing sites where they are released and mate with wild-type *Aedes aegypti* females that do not carry *Wolbachia*. After mating, the bacteria prevents the embryos from developing properly so the mosquitos cannot successfully reproduce. In February 2016, EPA published a Notice of Receipt of the university's application and took public comment. EPA concluded that the experimental work initially approved for the EUP in 2015 presented minimal risks to non-target organisms and the environment. The additional sites and extended time do not raise any new risk concerns for EPA.

As the *Aedes aegypti* mosquitoes are known to carry numerous diseases, including the Zika virus, it is important to note that information gathered under this EUP may lead to a new tool to help control mosquitoes that carry diseases. Documents related to this EUP, including scientific assessments, are available in Docket EPA-HQ-OPP-2015-0374 on www.regulations.gov.

EPA has issued, amended, and/or extended other experimental use permits using this same technology in another mosquito species, *Aedes polynesiensis* or *Aedes albopictus* in 2012, 2013, and 2014. Information on those EUPs is available in docket number EPA-HQ-OPP-2012-0181 and docket number EPA-HQ-OPP-2013-0254 at www.regulations.gov.

Debby Sisco
Office of Pesticide Programs (7501P)
Ethics Officer and Special Assistant to the Director
Room 12651 Potomac Yard South (office: 703 308-8121; cell: 571 317-4823)

From: Keigwin, Richard
Sent: Wednesday, August 31, 2016 9:46 AM
To: Sisco, Debby <Sisco.Debby@epa.gov>
Cc: Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Keltz, Colleen <Keltz.Colleen@epa.gov>
Subject: RE: For your review -- OPP Update -- Wolbachia EUP Aegypti Mosquitoes

Take out the reference to elimination of mosquitoes. The efficacy is low.

Rick Keigwin
Deputy Director for Programs
Office of Pesticide Programs

Sent from my Windows Phone

From: Keigwin, Richard
Sent: 8/30/2016 5:41 PM
To: Sisco, Debby
Cc: Dinkins, Darlene; Keltz, Colleen
Subject: RE: For your review -- OPP Update -- Wolbachia EUP Aegypti Mosquitoes

No comments.

From: Sisco, Debby
Sent: Tuesday, August 30, 2016 3:30 PM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Keltz, Colleen <Keltz.Colleen@epa.gov>
Subject: For your review -- OPP Update -- Wolbachia EUP Aegypti Mosquitoes

– BPPD is trying to announce this (and have everything in the docket) by end of next week

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Debby Sisco
Office of Pesticide Programs (7501P)
Ethics Officer and Special Assistant to the Director
Room 12651 Potomac Yard South (office: 703 308-8121; cell: 571 317-4823)

From: Keltz, Colleen
Sent: Tuesday, August 30, 2016 2:55 PM
To: Sisco, Debby <Sisco.Debby@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>; Overbey, Dian <Overbey.Dian@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>
Subject: OPP Update -- Wolbachia EUP Aegypti Mosquitoes

Hi Debby – BPPD is trying to announce this (and have everything in the docket) by end of next week. Thoughts on the update below?

EPA Grants Extension of Experimental Use Permit for ‘*Wolbachia* Mosquito’

EPA has approved the amendment and extension of an existing experimental use permit (EUP) for *Wolbachia pipientis*-infected *Aedes aegypti* mosquitoes. *Wolbachia* is a naturally occurring bacteria commonly found in most insect species, but not in the *Aedes aegypti*. The EUP was issued to the University of Kentucky’s Department of Entomology (UKDE) in October 2015 for limited testing in Fresno County, California. The updated EUP, which is authorized only California and Florida, will evaluate the *Wolbachia pipientis* bacteria’s effectiveness in suppressing and eliminating *Aedes aegypti* mosquitoes at particular sites in Fresno and Orange County in California and Monroe County in Florida.

Wolbachia pipientis is a bacteria that generally does not occur in wild populations of *Aedes aegypti*. This strain of *Wolbachia* is extracted from *Aedes albopictus* embryos and microinjected into *Aedes aegypti* embryos. Male mosquitoes are separated from female mosquitoes and shipped to testing sites where they are released and mate with wild-type *Aedes aegypti* females that do not carry *Wolbachia*. After mating, the bacteria prevents the embryos from developing properly so the mosquitos cannot successfully reproduce.

Upon receiving the request from UKDE to amend and extend the EUP in February 2016, EPA published a Notice of Receipt and took public comment. EPA has concluded that the experimental work initially approved for the EUP in 2015 presented minimal risks to nontarget organisms and the environment. The additional sites and extended time did not raise any new risk concerns for EPA.

As the *Aedes aegypti* mosquitoes are known to carry numerous diseases, including the Zika virus, it is important to note that information gathered under this EUP may lead to a new tool to help control mosquitoes that carry diseases.

Documents related to this EUP, including scientific assessments, are available in Docket EPA-HQ-OPP-2015-0374 on www.regulations.gov.

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